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09/918,063	07/30/2001	Eric R. Weber	DI-12	2551

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	7

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,063	Applicant(s) WEBER ET AL.	
	Examiner Frank W Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 and 4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-6 and 10-12 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that: (1) "since the method of Group II requires the nucleic acid molecule of Group I, these groups are sufficiently small and so closely related as to be capable of examination together."; and (2) "[A]pplicants further note that SEQ ID NO: 10 represents the complement of SEQ ID No: 8 and argue that SEQ ID NO: 10 should therefore be examined with SEQ ID Nos 8 and 9.".

These arguments have been fully considered and the examiner agreed to examine SEQ ID Nos: 8-10 together. However, even "the method of Group II requires the nucleic acid molecule of Group I", as clearly stated in previous office action, the product (an isolated nucleic acid molecule of claim 1) as claimed can be used in a materially different process of using that product such as using as a hybridization probe. Furthermore, the search required for Group II such as producing a recombinant protein is not required for Group II.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 1 is objected to because of the following informalities: " (a)" in line 2 of the claim should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (pages 1-93) provides adequate written description for isolated nucleic acid molecules consisting of the nucleotide sequence of SEQ ID Nos: 8 and 10 and an isolated nucleic acid molecule encoding a protein consisting of SEQ ID NO. 9 which served as a tumor antigen recited in claims 1 and 10. However, the specification fails to adequately describe: (1) any kind of isolated nucleic acid molecule comprising a nucleic acid sequence selected from the

group consisting of SEQ ID Nos: 8 and 10; and (2) any kind of isolated nucleic acid molecule encoding a protein comprising SEQ ID NO. 9. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In this instant case, an isolated nucleic acid in claims 1 and 2 was read as any kind of isolated nucleic acid that is larger than a nucleic acid consisting of SEQ ID Nos: 8 or 10, and an isolated nucleic acid in claims 10-12 was read as any kind of isolated nucleic acid encoding a protein that is larger than an amino acid sequence consisting of SEQ ID No: 9. Although the specification adequately describes isolated nucleic acid molecules consisting of the nucleotide sequence of SEQ ID Nos: 8 and 10 and an isolated nucleic acid molecule encoding a protein consisting of SEQ ID NO. 9, claims 1 and 2 encompass numerous unknown and unidentified nucleic acids that have polynucleotide sequence adding to 5', 3' and/or within the nucleotide sequence of SEQ ID Nos: 8 and 10 or nucleic acids encoding various variants of SEQ ID Nos. 8 and 10 that miss from the disclosure while claims 10-12 encompass numerous unknown and unidentified proteins /polypeptides that have amino acid sequence adding to 5', 3' and/or within the amino acid sequence of SEQ ID No: 9 or proteins /polypeptides encoding various variants of

SEQ ID No. 9 that miss from the disclosure. It is unclear whether these variants of SEQ ID Nos: 8-10 can still serve as a tumor antigen as SEQ ID Nos: 8-10 do. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all the possible variant nucleic acid or protein/polypeptide sequences which would be homologous or hybridize but do not correspond to nucleotide sequence consisting of SEQ ID No: 8 and 10 or encoding a protein consisting of SEQ ID No. 9 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.* Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated polynucleotide consisting of SEQ ID No: 8 or 10 and an isolated nucleic acid molecule encoding a protein consisting of SEQ ID NO. 9 in claims 1, 2 and 10-12 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-5 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-5 are rejected as vague and indefinite because it is unclear that "the nucleic acid" in claim 2 and "a nucleic acid" in claims 3-5 is "an isolated nucleic acid" or " a nucleic acid molecule consisting of a nucleic acid sequence selected from the group consisting of SEQ ID NO: 8 and SEQ ID No: 10". Please clarify.

Claim 11 is rejected as vague and indefinite because it is unclear that "the nucleic acid" in claim 11 is "an isolated nucleic acid" or " a nucleic acid molecule complementary to a nucleic acid molecule of (a) or (b)". Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanicola-Nadel *et al.,* (WO 98/53071, published on November 26, 1998).

Sanicola-Nadel *et al.,* teach modulators of tissue regeneration.

Regarding claim 10, since amino acids 36-51 (16 amino acids) in SEQ ID NO: 85 (a cDNA clone of novel class of rat Kidney Injury-associated Molecules) was 100% identical to amino acids 33-48 of SEQ ID NO: 9 of this instant application (see pages 3, 23-26, and 179-181), SEQ ID NO: 85 was considered as an isolated nucleic acid molecule encoding a protein comprising an at least 6 consecutive amino acid portion identical in sequence to an at least 6 consecutive amino acid portion of SEQ ID NO: 9 as recited in (b) of claim 10. Also, since nucleotide sequences 359-379 in SEQ ID NO: 85 was 100% identical to nucleotide sequences 96-116 of SEQ ID NO: 8 of this instant application, SEQ ID NO: 85 was considered as an

isolated nucleic acid molecule complementary to a nucleic acid molecule of (a) as recited in (c) of claim 10.

Regarding claim 12, Sanicola-Nadel *et al.,* taught a cDNA of rat Kidney Injury-associated Molecule and physiological acceptable carrier, vehicle or excipient (see page 6, third paragraph).

Therefore, Sanicola-Nadel *et al.,* teach all limitations recited in claims 10 and 12.

10. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sanicola-Nadel *et al.,* (November 26, 1998).

The teaching of Sanicola-Nadel *et al.,* have been summarized previously, *supra.*

Regarding claim 1, since nucleotide sequences 255-407 in SEQ ID NO: 85 was 84.3% identical to nucleotide sequences 1-144 of SEQ ID NO: 8 of this instant application, SEQ ID NO: 85 was considered as a cDNA molecule that hybridizes with a nucleic acid molecule consisting of a nucleic acid sequence selected from the group consisting of SEQ ID NO: 8 and SEQ ID NO: 10. Although Sanicola-Nadel *et al.,* did not disclose a cDNA made from canine and a hybridization condition as recited in claim 1, it was known that, if this claims was a product-by-process claim, it was well established that even though product-by process claims were limited by and defined by the process, the determination of the patentability of the product was based on the product itself. The patentability of a product did not depend on its method of production. If the product in the product-by-process claim was the same as or obvious from a product of the prior art, the claim was unpatentable even though the prior product was made by a different process."*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 3, 5, and 6, Sanicola-Nadel *et al.,* taught a cDNA of rat Kidney Injury-associated Molecule (KIM), a prokaryotic or eukaryotic host cell comprising an internalized vector having KIM-encoding nucleic acid insert, Kin fusion protein, physiological acceptable carrier, vehicle or excipient (see third paragraph in pages 3 and 6). Although Sanicola-Nadel *et al.,* did not directly show that KIM-encoding nucleic acid insert was operatively to a transcription control sequence as recited in claim 3, in the absence of convincing evidence to the contrary, this limitation was considered to be inherent to the reference taught Sanicola-Nadel *et al.,* since the most expression vector had a promoter to control the expression of its insert. For example, see pGEM-4Z vector from Promega catalog (1999, page 15.7).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanicola-Nadel *et al.*, as applied to, claims 1, 3, 5, 6, 10, and 12 above, and further in view of Lathe *et al.,* (US Patent No.6,007,806, filed on December 12, 1997).

The teaching of Sanicola-Nadel *et al.,* have been summarized previously, *supra.*

Sanicola-Nadel *et al.*, do not disclose a recombinant virus as recited in claim 4.

Lathe *et al.,* do teach to make a recombinant virus having coding sequence (cDNA) of a tumor specific antigen (see columns 6 and 7).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a recombinant virus having a coding sequence of a protein as recited in claim 1 in view of the prior art of Sanicola-Nadel *et al.,* and Lathe *et al.*. One having ordinary skill in the art would have

been motivated to modify the product made by Sanicola-Nadel *et al.,* because a method for making a recombinant virus having a coding sequence of a protein was known in the art at the time the invention was made and the simple replacement of the coding sequence of one kind of protein (i.e., KIM cDNA) from the coding sequence of another protein (ie., cDNA consisting of SEQ ID No. 8) would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG

94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
August 22, 2002

ETHAN C. WHISENANT
PRIMARY EXAMINER